

IN THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

CATHERINE ANTUNES,

Plaintiff-Appellant,

v.

XAVIER BECERRA, *et al.*,

Defendants-Appellees.

On Appeal from the United States District Court
for the Western District of Virginia

BRIEF FOR FEDERAL APPELLEES

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STATEMENT OF JURISDICTION

As relevant to the claims at issue here, plaintiff invoked the district court's jurisdiction under 5 U.S.C. § 702, as well as 28 U.S.C. §§ 1331, 1343(a)(4). JA 10. As explained below, the district court lacked jurisdiction over those claims because plaintiff does not have standing to sue the federal government and the relevant agency actions are committed to agency discretion by law. *See infra* pp. 10-22. The district court dismissed plaintiff's complaint on September 12, 2022. JA 77. Plaintiff timely appealed on Monday, November 14, 2022. JA 7, JA 78; *see* Fed. R. App. P. 4(a)(1)(B) (60-day time limit). This Court has jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUE

Plaintiff Catherine Antunes, a nurse formerly employed by the University of Virginia Health System, was terminated from her employment when she refused to receive a COVID-19 vaccination or apply for a medical or religious exemption in accordance with her employer's vaccine requirement. She has now brought claims against not only the University of Virginia but also against the federal government. The claims against the federal government assert that the Secretary of Health and Human Services improperly declared a COVID-19 public health emergency and improperly issued Emergency Use Authorizations for COVID-19 vaccinations without conditions designed to ensure that recipients would not be subject to vaccine mandates from third parties. The issue presented is whether the district court correctly

dismissed Antunes’s claims against the federal government for lack of standing and because the relevant agency actions are committed to agency discretion by law.

PERTINENT STATUTES AND REGULATIONS

Pertinent statutes and regulations are reproduced in the addendum to this brief.

STATEMENT OF THE CASE

A. Statutory and Regulatory Background

The Public Health Service Act generally prohibits the introduction of biological products such as vaccines into interstate commerce absent an approved biologics license application from the U.S. Food and Drug Administration (FDA). *See* 42 U.S.C. § 262(a)(1)(A), (i)(1). To obtain a license, a manufacturer must submit an application to FDA, which the agency reviews to determine, among other things, whether the product is “safe, pure, and potent.” *Id.* § 262(a)(2)(C).

Separately, the Federal Food, Drug, and Cosmetic Act provides that FDA may authorize biological products such as vaccines that are “intended for use in an actual or potential emergency,” “[n]otwithstanding” the Public Health Service Act’s licensing provisions. 21 U.S.C. § 360bbb-3(a)(1). The Secretary of Health and Human Services may declare that circumstances justifying an emergency use authorization (EUA) exist if, among other circumstances, the Secretary determines that there is a current or impending public health emergency “that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents.” *Id.* § 360bbb-3(b)(1). FDA may then issue an EUA for vaccines or

other products intended for use in diagnosing, treating, or preventing the serious or life-threatening disease or condition that caused the emergency. *Id.* § 360bbb-3(c)(1).

To issue an EUA, FDA must find that it is reasonable to believe that the vaccine is effective “based on the totality of scientific evidence . . . , including data from adequate and well-controlled clinical trials, if available,” and that the product’s benefits outweigh its risks. 21 U.S.C. § 360bbb-3(c)(2). In addition, the statute provides that, “[w]ith respect to the emergency use of an unapproved product,” FDA, “to the extent practicable,” shall “establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health,” including “[a]ppropriate conditions designed to ensure that individuals to whom the product is administered are informed” that “the Secretary has authorized the emergency use of the product”; are informed of “the significant known and potential benefits and risks of such use”; and are informed “of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.” *Id.* § 360bbb-3(e)(1)(A). Congress expressly provided that all “[a]ctions under the authority of” the relevant section of the statute are “committed to agency discretion.” *Id.* § 360bbb-3(i).

B. Factual and Procedural Background

1. In February 2020, the Secretary of Health and Human Services made a determination of a “public health emergency . . . that involves a novel (new)

coronavirus,” known as SARS-CoV-2, the virus that causes COVID-19. 85 Fed. Reg. 7316, 7317 (Feb. 7, 2020). Shortly thereafter, the Secretary declared that “circumstances exist justifying the authorization of emergency use of drugs and biological products” under § 360bbb-3(b)(1). 85 Fed. Reg. 18,250, 18,250-51 (Apr. 1, 2020).

In December 2020, FDA issued two EUAs for vaccines for the prevention of COVID-19: one manufactured by Pfizer, Inc. and BioNTech Manufacturing GmbH and one manufactured by ModernaTX, Inc. *See* 86 Fed. Reg. 5200, 5200 (Jan. 19, 2021) (providing notice of EUA issuance). In February 2021, FDA also issued an EUA for a vaccine manufactured by Janssen Biotech, Inc. for the prevention of COVID-19. *See* 86 Fed. Reg. 28,608, 28,610 (May 27, 2021). Those EUAs have since been reissued a number of times. *See* FDA, *Emergency Use Authorization*, <https://perma.cc/46QH-9J28> (last updated Mar. 14, 2023) (listing EUAs).

On August 23, 2021, FDA approved a license for the Pfizer-BioNTech vaccine. *See* FDA News Release, *FDA Approves First COVID-19 Vaccine* (Aug. 23, 2021), <https://perma.cc/5Q5J-GP9H>. On January 31, 2022, FDA approved a license for the Moderna vaccine. *See* FDA News Release, *FDA Takes Key Action by Approving Second COVID-19 Vaccine* (Jan. 31, 2022), <https://perma.cc/K65B-ZDYY>. Since those approvals, both Pfizer-BioNTech and Moderna have distributed EUA-authorized vaccines and licensed vaccines. Although the licensed products “have the same formulation” as the EUA vaccines that are authorized for the same age groups

and conditions of use, they are “legally distinct with certain differences that do not impact safety or effectiveness.” FDA, Letter of Authorization to ModernaTX, Inc. 19 (Dec. 8, 2022), <https://perma.cc/C3HQ-2CWM>; *see also* FDA, Letter of Authorization to Pfizer, Inc. 20 (Dec. 8, 2022), <https://perma.cc/UJ8H-YCTP> (similar).

2. As alleged in her complaint, plaintiff Catherine Antunes was employed by the University of Virginia’s healthcare system (UVA Health) as a nurse beginning in January 2020. JA 15. On August 25, 2021, two days after FDA approved a license for the Pfizer-BioNTech vaccine, UVA Health notified its employees that it would require all employees “without a religious or medical exemption to be vaccinated against COVID-19 by November 1, 2021.” JA 15-16 (quotation omitted). The notification further informed employees that those who did not meet that November 1 deadline would be subject to discipline, including potential termination. JA 16.

When Antunes did not receive any COVID-19 vaccination by the November 1 deadline, UVA Health informed her that she would be suspended pending verification of her vaccination status. JA 17. On November 9, UVA Health terminated her employment. JA 17.

3. Antunes filed this lawsuit challenging her termination. In her operative complaint, Antunes brings two claims against the U.S. Department of Health and Human Services, FDA, the Secretary of Health and Human Services, and the Commissioner of Food and Drugs (along with additional claims against UVA that this

brief does not address). First, she claims (in Count One) that the federal defendants' authorization of the vaccines for emergency use violated the Federal Food, Drug, and Cosmetic Act, both because the Secretary allegedly failed to indicate in his emergency declaration that COVID-19 involves "a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents" and because the Secretary failed to "ensure that" the EUA-authorized vaccines were administered without any "economic or other coercion or force." JA 17-19. Second, she claims (in Count Three) that the government "has set up a discriminatory framework for the administration of the vaccines," in violation of equal protection, because agency regulations generally require that investigators conducting clinical pharmaceutical trials obtain participants' informed consent without coercion or undue influence but the EUAs did not similarly forbid UVA Health (or other employers) from using "coercive influence" to require employees to obtain the EUA-authorized vaccines. JA 20-22.

The district court dismissed Antunes's claims against the federal defendants for lack of jurisdiction. First, the court concluded that Antunes lacked standing to pursue her claims. JA 62-65. To establish standing, a "plaintiff must have (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016); *see* JA 62.

Applying that framework here, the district court concluded that Antunes failed to show either that her claimed injury (her termination) was fairly traceable to the federal defendants or that it would be redressed by a favorable decision on the merits of her claims against the federal defendants. With respect to traceability, the court explained that Antunes's termination resulted from UVA Health's own independent decision to implement and enforce a vaccination policy and was not fairly traceable to the federal government's challenged conduct: issuing EUAs for the three COVID-19 vaccines. JA 63-65. And with respect to redressability, the court explained that Antunes sought a declaration that FDA's issuance of the EUAs was unlawful but that Antunes had failed to "allege any facts that such a declaration" would redress her injury "by causing UVA Health to re-hire" her. JA 64-65.

Second, the district court concluded that Antunes's claims should independently be dismissed for lack of jurisdiction because the Secretary's decision to authorize the EUAs is committed to agency discretion by law. The court explained that the Administrative Procedure Act (APA) exempts from its coverage "agency action [that] is committed to agency discretion by law," 5 U.S.C. § 701(a)(2), and that, under this Court's precedent, district courts therefore generally lack subject matter jurisdiction over claims challenging action that is committed to agency discretion. JA 66. Here, the statutory provision governing EUAs expressly provides that the Secretary's actions "under the authority of this section" are "committed to agency discretion." 21 U.S.C. § 360bbb-3(i). Because Antunes's claims challenge the

Secretary's actions under the authority of that section, review under the APA is not available. *See* JA 66. And because Antunes failed to identify any other appropriate basis for subject matter jurisdiction, the district court concluded that her claims against the federal defendants had to be dismissed for lack of jurisdiction. JA 67.

The district court also dismissed the claims against the University of Virginia and entered final judgment. This appeal followed.

SUMMARY OF ARGUMENT

I. The district court correctly dismissed Antunes's claims against the federal government for lack of standing. To establish Article III standing, a plaintiff must demonstrate an "injury in fact" that is "fairly traceable to the challenged action of the defendant" and that would "likely" be "redressed by a favorable decision." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992) (alterations and quotations omitted). Here, Antunes's claimed injury is UVA Health's decision to terminate her employment. But that injury is not traceable to any of the federal government's actions that she seeks to challenge, nor would her termination be redressed by a favorable decision on those claims.

First, Antunes's injury is not fairly traceable to the federal government. When a plaintiff's claimed injury is the result of actions by a third party rather than the defendant, traceability is "substantially more difficult" to establish. *Lane v. Holder*, 703 F.3d 668, 673 (4th Cir. 2012) (quotation omitted). Such injury will generally only suffice if the challenged conduct has a "determinative or coercive effect" on the third

party, *Bennett v. Spear*, 520 U.S. 154, 169 (1997). And here, Antunes fails to demonstrate that any of FDA’s actions in issuing the COVID-19 vaccine EUAs had any such determinative or coercive effect on UVA Health. Instead, to the contrary, UVA Health decided in its own discretion to implement a vaccine mandate and to terminate employees who did not comply. Thus, Antunes’s harm is not directly traceable to the federal government.

Second, Antunes’s injury would not be likely redressed by a favorable decision on her claims against the government. On those claims, Antunes seeks a judicial order setting aside the government’s actions and declaring them unlawful. *See* JA 24. But nothing about such an order would “compel” UVA Health to rescind Antunes’s termination or rehire her. *Frank Krasner Enters., Ltd. v. Montgomery County*, 401 F.3d 230, 236 (4th Cir. 2005). In response to the district court’s similar conclusion, Antunes suggests in her opening brief (at 26-27) that the Department of Health and Human Services might be able to convince UVA Health to re-hire her by, for example, conditioning unrelated funding on her re-hiring. But Antunes does not seek and could not obtain any relief compelling the Department to undertake such efforts, and her suggestion thus only underscores the gap between the relief she does request and her injury.

II. The district court correctly recognized that Antunes’s claims against the federal government are independently jurisdictionally barred because the APA does not provide any avenue to challenge actions that are “committed to agency discretion

by law.” 5 U.S.C. § 701(a)(2). Here, Antunes seeks to challenge actions that the Secretary and FDA took pursuant to 21 U.S.C. § 360bbb-3 in declaring a public health emergency and issuing EUAs. But Congress has expressly provided that all “[a]ctions under the authority of this section . . . are committed to agency discretion.” 21 U.S.C. § 360bbb-3(i). Thus, Antunes cannot maintain her APA claims challenging those actions, and the district court correctly dismissed them.

STANDARD OF REVIEW

This Court reviews de novo the district court’s dismissal for lack of subject matter jurisdiction of plaintiff’s claims against the federal government. *Tillman v. Resolution Tr. Corp.*, 37 F.3d 1032, 1034 (4th Cir. 1994).

ARGUMENT

I. Antunes Lacks Standing to Pursue Her Claims Against the Federal Government

“The law of Art[icle] III standing is built on a single basic idea—the idea of separation of powers.” *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2203 (2021) (quotation omitted). “Under Article III, federal courts do not adjudicate hypothetical or abstract disputes” and “do not exercise general legal oversight of the Legislative and Executive Branches.” *Id.* Instead, to establish standing, a plaintiff must prove (1) that she has “suffered an injury in fact”; (2) that the injury is “fairly traceable to the challenged action of the defendant, and not the result of the independent action of some third party not before the court”; and (3) that it is “likely, as opposed to merely

speculative, that the injury will be redressed by a favorable decision.” *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992) (alterations and quotations omitted). In addition, “standing is not dispensed in gross”; instead, a plaintiff must demonstrate that the standing requirements are met “for each claim [s]he seeks to press and for each form of relief that is sought.” *Town of Chester v. Laroe Estates, Inc.*, 581 U.S. 433, 439 (2017) (quotation omitted).

Here, the injury that Antunes complains about is the termination of her employment by UVA Health when she chose not to become vaccinated against COVID-19. But her claims against the federal government do not directly challenge that termination; instead, they challenge FDA’s issuance of Emergency Use Authorizations for three vaccines and the conditions that FDA attached to those EUAs. *See* JA 17-22. As the district court correctly found, Antunes’s claimed injury is not fairly traceable to the conduct that her claims against the federal government challenge, nor is it likely that any favorable decision on those claims would redress her injury.

A. The district court correctly recognized that Antunes has failed to demonstrate that her claimed injury—her termination by UVA Health—is “fairly traceable” to the federal government conduct that she challenges—FDA’s issuance of EUAs for three of the COVID-19 vaccines.

1. As the Supreme Court has repeatedly emphasized, to suffice for standing, a plaintiff’s injury must be “fairly traceable to the challenged action of the defendant,

and not the result of the independent action of some third party not before the court.” *Lujan*, 504 U.S. at 560-61 (alterations and quotation omitted). The Supreme Court has further admonished that, in pleading traceability, “much more is needed” when an injury “depends on the unfettered choices made by independent actors not before the courts and whose exercise of broad and legitimate discretion the courts cannot presume either to control or to predict.” *Id.* at 562 (quotation omitted). In short, when the plaintiff “is not the direct subject of government action” but instead complains of an injury that is mediated through the government’s regulation of somebody else, demonstrating standing to pursue claims against the government will ordinarily be “substantially more difficult.” *Lane v. Holder*, 703 F.3d 668, 673 (4th Cir. 2012) (quotation omitted). Such mediated injury will generally only suffice for standing purposes if the challenged government conduct has a “determinative or coercive effect upon the action” that directly causes the plaintiff’s injury. *Bennett v. Spear*, 520 U.S. 154, 169 (1997).

Applying these principles, this Court has rejected plaintiffs’ attempts to bring suit against governmental entities when they are directly harmed by private parties’ independent decisions, even when those plaintiffs argued that the government’s actions created the conditions that engendered the harm. For example, in *Lane*, residents of the District of Columbia challenged a federal statute requiring that interstate transfers of handguns be routed through a federal firearms licensee in the purchaser’s home state. *See* 703 F.3d at 670. The plaintiffs alleged that they had

purchased, and intended to continue purchasing, handguns from a licensed dealer in Virginia but that, as a result of the federal statute, those purchases had to be routed through a licensee in the District of Columbia who charged plaintiffs a transfer fee. *Id.* at 671. This Court concluded that the plaintiffs' claimed harm was not "traceable to the challenged" statute. *Id.* at 673. The Court explained that "[n]othing in the challenged" federal statute or regulations "directs [licensees] to impose such charges." *Id.* at 674. Thus, even though the federal statute prohibited plaintiffs from purchasing handguns directly from the Virginia dealer and so created the conditions that gave the District of Columbia licensee the opportunity to charge plaintiffs a fee, the Court concluded that "the costs the plaintiffs complain of are not traceable to the laws they challenge" but instead to the licensee that "charge[d] transfer fees." *Id.*

Similarly, in *Frank Krasner Enterprises, Ltd. v. Montgomery County*, 401 F.3d 230, 232 (4th Cir. 2005), this Court rejected a gun-show promoter's claims of standing to challenge a county law denying public funding to venues that display and sell guns. Although the privately owned venue specifically cited the law in declining to continue renting space to the plaintiff for its gun shows and the Court acknowledged that the county "law makes it more expensive—perhaps prohibitively so—for the [venue] to lease space to" the plaintiff, *id.* at 232-33, 236, this Court concluded that the plaintiff's injury was not fairly traceable to the county's actions. The Court explained that the claimed injury was "not directly linked to the challenged law because an

intermediary”—the venue—“stands directly between the plaintiffs and the challenged conduct in a way that breaks the causal chain.” *Id.* at 236.

In addition, several courts have dismissed on standing grounds claims quite factually similar to those asserted here. Particularly analogous is the Sixth Circuit’s recent decision in *Children’s Health Defense v. U.S. FDA*, No. 21-6203, 2022 WL 2704554 (6th Cir. July 12, 2022), *cert. denied*, No. 22-584 (Feb. 21, 2023). There, plaintiffs who claimed to be injured by the Department of Defense’s decision to implement a vaccination mandate brought suit against FDA, contending that FDA had illegally licensed the Pfizer-BioNTech vaccine while simultaneously extending its EUA. *See id.* at *1-2. In affirming the district court’s dismissal for lack of standing, the Sixth Circuit explained that “plaintiffs’ alleged injuries are not fairly traceable to FDA’s actions” because “FDA has not required the general public to be vaccinated, FDA has not required military servicemembers to be vaccinated, and FDA does not control the military.” *Id.* at *3-4. In short, FDA has “not imposed any kind of mandate affecting the” plaintiffs, and so their alleged injuries stemmed only from the Department of Defense’s independent decision to adopt a vaccination requirement. *Id.* Other cases have similarly recognized the distinction between requirements that individuals be vaccinated, on the one hand, and FDA’s authorization of the vaccine, on the other. *See e.g., Null v. U.S. FDA*, No. 09-cv-1924, 2009 WL 10744069, at *3 (D.D.C. Nov. 10, 2009) (holding that New York State vaccine mandate for nurses “cannot be attributed to the federal government . . . just because the federal

government approved a vaccine as safe for human consumption”); JA 63 (collecting additional similar cases).

2. This case is on all fours with the various prior cases involving challenges to vaccine authorization by individuals claiming injury from vaccine mandates, and it presents a weaker claim to standing than this Court’s prior cases that were dismissed on standing grounds in other contexts. The district court properly concluded that Antunes has failed to show that her termination is “fairly traceable” to the federal government’s challenged conduct.

Nowhere does Antunes allege or argue that she is the direct subject of any federal government regulation. Instead, she “alleges injury based on UVA Health’s suspension and subsequent termination of her employment.” JA 64. And this alleged injury is indisputably directly traceable not to any action by the federal government but instead to UVA Health’s own independent decisions to impose a vaccination requirement for its employees and to terminate Antunes for failing to comply with that requirement.

Put another way, Antunes has not provided “any allegations that Federal Defendants participated in UVA Health’s decision to suspend or terminate her.” JA 64. Nor has (or could) Antunes alleged that any portion of FDA’s or the Secretary’s challenged conduct—the determination of a public health emergency, the issuance of the EUAs, and not conditioning the EUAs on some requirement related to coercion—“directs [UVA Health] to impose” a vaccination requirement or terminate

employees who are not vaccinated. *Cf. Lane*, 703 F.3d at 674. Thus, UVA Health “stands directly between [Antunes] and the [federal government’s] challenged conduct,” *Krasner*, 401 F.3d at 236, and Antunes’s harm is not fairly traceable to the federal government. As noted above, other courts considering similar claims have reached the same conclusion.

B. The district court also correctly concluded that Antunes lacks standing to pursue her claims against the federal government for the additional and independent, though related, reason that she has failed to demonstrate that her claimed harm would be redressed by the relief she seeks on those claims.

As explained, to establish standing, a plaintiff must demonstrate that it is “likely, as opposed to merely speculative, that the injury” complained of “will be redressed by a favorable decision.” *Lujan*, 504 U.S. at 561 (quotation omitted). As with traceability, redressability is “ordinarily substantially more difficult to establish” where, as in this case, “a plaintiff’s asserted injury arises from the government’s allegedly unlawful regulation (or lack of regulation) of *someone else*.” *Id.* at 561-62 (quotation omitted).

Here, Antunes’s claimed injury is her termination by UVA Health. Conversely, the relief that she seeks against the federal government is for the court to “[h]old unlawful and set aside” the federal government’s allegedly “unequal treatment of similarly situated classes of vaccine recipients” and to “[i]ssue declaratory relief declaring” the federal government’s challenged actions “unlawful.” JA 24. But even if

the court “were to hear the case and hold for” Antunes on those claims—and grant that requested relief—that relief directed at FDA’s previous issuance of EUAs would “not compel” UVA Health to re-hire Antunes. *Krasner*, 401 F.3d at 236; *cf. Children’s Health Def.*, 2022 WL 2704554, at *4 (concluding that an order requiring FDA to revoke its licensure of the Pfizer-BioNTech vaccine would not require the Department of Defense to revoke its own vaccination mandate and thus would “not redress [plaintiffs’] alleged injuries”). And Antunes has not even attempted to demonstrate that UVA Health would likely react to any such relief by choosing to re-hire those employees who were terminated for a previous failure to comply with UVA Health’s vaccination mandates, even if such voluntary third-party reactions were sufficient for redressability purposes.

C. Antunes’s failure to demonstrate standing is only underscored by her discussion of the issue in her opening brief (at 25-27). There, she suggests only that the Department of Health and Human Services might be able to devise a regulatory enforcement scheme that “work[s] to prevent incidents like what occurred with UVA and Ms. Antunes,” such as by “tying important grants and funding streams (*e.g.* Medicare payments) to the existence of such protections at grantee entities.” Br. 26. It is unclear why the possibility of such a scheme would render Antunes’s injury traceable to the agency action that she actually challenges—issuance of the EUA. And as to redressability, Antunes nowhere even attempts to demonstrate that it is likely that the Department would devise such a scheme if a court declared FDA’s

previous issuances of the EUAs unlawful—much less that the Secretary could or would exercise his enforcement discretion to enforce such a scheme against UVA Health if it failed to re-hire Antunes and that UVA Health would respond by re-hiring her. Nor has Antunes sought (nor could she plausibly seek) an injunction compelling the Secretary or FDA to exercise its enforcement authority to seek to persuade UVA Health to re-hire her. *Cf. Heckler v. Chaney*, 470 U.S. 821, 835 (1985). Thus, even taking Antunes’s suggestion of a hypothetical new enforcement scheme on its own terms, she has failed to link the relief that she has actually sought against the federal government to any redress of her injuries and her claims must be dismissed for lack of standing.

II. The Relevant Actions Are Committed to Agency Discretion by Law

The district court properly concluded that plaintiff’s claims were independently jurisdictionally barred because they seek to challenge actions that are committed to agency discretion by law.

A. Under the APA, a plaintiff may not obtain judicial review of agency action “committed to agency discretion by law.” 5 U.S.C. § 701(a)(2). This Court’s precedents establish that this limitation on judicial review is jurisdictional; thus, federal courts lack subject matter jurisdiction over a matter challenging agency action that is committed to the agency’s discretion. *See Angelex Ltd. v. United States*, 723 F.3d 500, 506 (4th Cir. 2013). In granting FDA authority to issue EUAs, Congress expressly

provided that all “[a]ctions under the authority of this section . . . are committed to agency discretion.” 21 U.S.C. § 360bbb-3(i). Congress thus could not have been clearer that determinations about EUAs, including the conditions that FDA attaches to their issuance, are matters that plaintiffs may not challenge through an APA suit.

But Antunes’s claims are directed at challenging actions that the Secretary or the agency took under the authority of § 360bbb-3: the declaration of an emergency justifying EUAs and the issuance of EUAs without certain non-coercion conditions that plaintiff believes were required. *See* 21 U.S.C. § 360bbb-3(b) (providing for emergency declarations); *id.* § 360bbb-3(c) (providing authority to issue EUAs); *id.* § 360bbb-3(e) (providing authority to attach conditions of authorization to EUAs). Thus, as the district court properly concluded, Antunes’s claims challenge actions committed to agency discretion by law and the courts lack jurisdiction to review them. JA 66; *see also* JA 66 (collecting additional analogous case law).

In resisting this conclusion on appeal, Antunes does not dispute that actions taken under § 360bbb-3 are generally committed to agency discretion by law; indeed, she admits that “she would not be able to challenge the Secretary’s final determination about an” EUA. Br. 28. But, Antunes contends, her claims are not “about anything ‘under the authority’ of the” statute and instead are challenges to the Secretary’s and the agency’s purported “determin[ation] that certain explicit terms of the statute do not apply to them, or that they are free to ignore them.” *Id.*

Antunes cannot, however, evade the EUA statute's, and the APA's, limitations are judicial review simply by framing her claims as challenges to the Secretary's compliance with the statute. As explained, § 360bbb-3 authorizes the Secretary to declare an emergency, to issue an EUA, and to attach conditions to an EUA, and § 360bbb-3(i) commits to agency discretion all "[a]ctions" taken "under the authority of this section." Arguments that the Secretary's emergency declaration and FDA's issuance of EUAs were inconsistent with the statute, even if credited, would not change the fact that those actions were undeniably actions taken "under the authority" of the statute and thus "committed to agency discretion," 21 U.S.C. § 360bbb-3(i), and the APA does not apply "to the extent that . . . agency action is committed to agency discretion by law," 5 U.S.C. § 701(a)(2). Antunes's apparent view that actions that are committed to agency discretion by law can be challenged on the ground that they violate the terms of the statute would impermissibly open up all manner of actions that Congress intended to shield from judicial review to challenge in court. Nearly any challenge to an action taken under the statute may be framed as a challenge that the action was not taken in conformity with the statute. Congress's determination that certain agency actions are committed to agency discretion—and thus should not be the subject of protracted litigation—would not mean very much if it were so easily circumvented.

B. At the end of her brief (at 28-30), Antunes argues the merits of her constitutional claim premised on the equal protection principles incorporated into the

Fifth Amendment’s Due Process Clause. These arguments do not resuscitate Antunes’s challenge; although provisions committing decisions to agency discretion do not preclude courts from “review[ing] allegations that an agency . . . acted unconstitutionally,” a plaintiff may not simply “bypass[] the reviewability exception in § 701(a)(2)” by attempting to reframe a fundamentally non-constitutional claim as a constitutional challenge. *Angelex*, 723 F.3d at 508 (quoting *Electricities of N.C., Inc. v. Southeastern Power Admin.*, 774 F.2d 1262, 1267 (4th Cir. 1985)). Antunes properly does not assert that her efforts to give her claim a constitutional dimension are grounds for exempting her from the judicial-review bar.

Antunes’s constitutional arguments are in any event plainly without merit. Antunes contends that FDA violated equal protection principles by generally requiring investigators conducting clinical trials to obtain informed consent from participants while not imposing any requirement in the COVID-19 vaccine EUAs that would preclude UVA Health’s vaccine mandate. Because “no fundamental right or suspect classification is at issue” in this case, Antunes’s claim must be reviewed under the rational-basis standard, which merely requires that the government action be “rationally related” to furthering a “legitimate” government end. *Siena Corp. v. Mayor & City Council*, 873 F.3d 456, 465 (4th Cir. 2017) (quotation omitted).

Imposing requirements on those conducting clinical trials that are not imposed on employers does not reflect an irrational distinction between similarly situated groups. Participants in clinical trials and the general public receiving an EUA-

authorized vaccine outside of a clinical trial are not similarly situated. The former group may be receiving a drug or placebo as part of a controlled experiment while the latter group is receiving a drug as part of their clinical care to prevent disease.

Consistent with that distinction, the EUA statute itself recognizes that “use of [an EUA] product within the scope of the authorization shall not be considered to constitute a clinical investigation” for purposes of the relevant federal statutes. 21 U.S.C. § 360bbb-3(k). And the general requirement that investigators who conduct clinical trials obtain informed consent is in any event not comparable to the sort of requirement that Antunes seeks to impose on an employer that is not itself administering any drug but instead seeks to condition continued employment on vaccination.

CONCLUSION

For the foregoing reasons, the judgment of the district court should be affirmed.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 5,342 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Word for Microsoft 365 in Garamond 14-point font, a proportionally spaced typeface.

s/ Sean R. Janda

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ADDENDUM

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21 U.S.C. § 360bbb-3A1

21 U.S.C. § 360bbb-3

§ 360bbb-3. Authorization for medical products for use in emergencies

(a) In general

(1) Emergency uses

Notwithstanding any provision of this chapter and section 351 of the Public Health Service Act [42 U.S.C. 262], and subject to the provisions of this section, the Secretary may authorize the introduction into interstate commerce, during the effective period of a declaration under subsection (b), of a drug, device, or biological product intended for use in an actual or potential emergency (referred to in this section as an “emergency use”).

(2) Approval status of product

An authorization under paragraph (1) may authorize an emergency use of a product that—

(A) is not approved, licensed, or cleared for commercial distribution under section 355, 360(k), 360b, or 360e of this title or section 351 of the Public Health Service Act [42 U.S.C. 262] or conditionally approved under section 360ccc of this title (referred to in this section as an “unapproved product”); or

(B) is approved, conditionally approved under section 360ccc of this title, licensed, or cleared under such a provision, but which use is not under such provision an approved, conditionally approved under section 360ccc of this title, licensed, or cleared use of the product (referred to in this section as an “unapproved use of an approved product”).

(3) Relation to other uses

An emergency use authorized under paragraph (1) for a product is in addition to any other use that is authorized for the product under a section of this chapter or the Public Health Service Act [42 U.S.C. 201 et seq.] referred to in paragraph (2)(A).

(4) Definitions

For purposes of this section:

(A) The term “biological product” has the meaning given such term in section 351 of the Public Health Service Act [42 U.S.C. 262].

(B) The term “emergency use” has the meaning indicated for such term in paragraph (1).

(C) The term “product” means a drug, device, or biological product.

(D) The term “unapproved product” has the meaning indicated for such term in paragraph (2)(A).

(E) The term “unapproved use of an approved product” has the meaning indicated for such term in paragraph (2)(B).

(b) Declaration of emergency or threat justifying emergency authorized use

(1) In general

The Secretary may make a declaration that the circumstances exist justifying the authorization under this subsection for a product on the basis of—

(A) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents;

(B) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces, including personnel operating under the authority of title 10 or title 50, of attack with—

(i) a biological, chemical, radiological, or nuclear agent or agents; or

(ii) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to United States military forces;

(C) a determination by the Secretary that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or

(D) the identification of a material threat pursuant to section 319F–2 of the Public Health Service Act [42 U.S.C. 247d–6b] sufficient to affect national security or the health and security of United States citizens living abroad.

(2) Termination of declaration

(A) In general

A declaration under this subsection shall terminate upon the earlier of—

(i) a determination by the Secretary, in consultation as appropriate with the Secretary of Homeland Security or the Secretary of Defense, that the circumstances described in paragraph (1) have ceased to exist; or

(ii) a change in the approval status of the product such that the circumstances described in subsection (a)(2) have ceased to exist.

(B) Disposition of product

If an authorization under this section with respect to an unapproved product ceases to be effective as a result of a termination under subparagraph (A) of this paragraph, the Secretary shall consult with the manufacturer of such product with respect to the appropriate disposition of the product.

(3) Advance notice of termination

The Secretary shall provide advance notice that a declaration under this subsection will be terminated. The period of advance notice shall be a period reasonably determined to provide—

(A) in the case of an unapproved product, a sufficient period for disposition of the product, including the return of such product (except such quantities of product as are necessary to provide for continued use consistent with subsection (f)(2)) to the manufacturer (in the case of a manufacturer that chooses to have such product returned); and

(B) in the case of an unapproved use of an approved product, a sufficient period for the disposition of any labeling, or any information under subsection (e)(2)(B)(ii), as the case may be, that was provided with respect to the emergency use involved.

(4) Publication

The Secretary shall promptly publish in the Federal Register each declaration, determination, and advance notice of termination under this subsection.

(5) Explanation by Secretary

If an authorization under this section with respect to an unapproved product or an unapproved use of an approved product has been in effect for more than 1 year, the Secretary shall provide in writing to the sponsor of such product an explanation of the scientific, regulatory, or other obstacles to approval, licensure, or clearance of such product or use, including specific actions to be taken by the Secretary and the sponsor to overcome such obstacles.

(6) Military emergencies

In the case of a determination described in paragraph (1)(B), the Secretary shall determine, within 45 calendar days of such determination, whether to make a declaration under paragraph (1), and, if appropriate, shall promptly make such a declaration.

(c) Criteria for issuance of authorization

The Secretary may issue an authorization under this section with respect to the emergency use of a product only if, after consultation with the Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable circumstances described in subsection (b)(1)), the Secretary concludes—

(1) that an agent referred to in a declaration under subsection (b) can cause a serious or life-threatening disease or condition;

(2) that, based on the totality of scientific evidence available to the Secretary, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that—

(A) the product may be effective in diagnosing, treating, or preventing—

(i) such disease or condition; or

(ii) a serious or life-threatening disease or condition caused by a product authorized under this section, approved or cleared under this chapter, or licensed under section 351 of the Public Health Service Act [42 U.S.C. 262], for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and

(B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under subsection (b)(1)(D), if applicable;

(3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition;

(4) in the case of a determination described in subsection (b)(1)(B)(ii), that the request for emergency use is made by the Secretary of Defense; and

(5) that such other criteria as the Secretary may by regulation prescribe are satisfied.

...

(e) Conditions of authorization

(1) Unapproved product

(A) Required conditions

With respect to the emergency use of an unapproved product, the Secretary, to the extent practicable given the applicable circumstances described in subsection (b)(1), shall, for a person who carries out any activity for which the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following:

(i) Appropriate conditions designed to ensure that health care professionals administering the product are informed—

(I) that the Secretary has authorized the emergency use of the product;

(II) of the significant known and potential benefits and risks of the emergency use of the product, and of the extent to which such benefits and risks are unknown; and

(III) of the alternatives to the product that are available, and of their benefits and risks.

(ii) Appropriate conditions designed to ensure that individuals to whom the product is administered are informed—

(I) that the Secretary has authorized the emergency use of the product;

(II) of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and

(III) of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.

(iii) Appropriate conditions for the monitoring and reporting of adverse events associated with the emergency use of the product.

(iv) For manufacturers of the product, appropriate conditions concerning recordkeeping and reporting, including records access by the Secretary, with respect to the emergency use of the product.

(B) Authority for additional conditions

With respect to the emergency use of an unapproved product, the Secretary may, for a person who carries out any activity for which the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following:

(i) Appropriate conditions on which entities may distribute the product with respect to the emergency use of the product (including limitation to distribution by government entities), and on how distribution is to be performed.

(ii) Appropriate conditions on who may administer the product with respect to the emergency use of the product, and on the categories of individuals to whom, and the circumstances under which, the product may be administered with respect to such use.

(iii) Appropriate conditions with respect to collection and analysis of information concerning the safety and effectiveness of the product with respect to the use of such product during the period when the authorization is in effect and a reasonable time following such period.

(iv) For persons other than manufacturers of the product, appropriate conditions concerning recordkeeping and reporting, including records access by the Secretary, with respect to the emergency use of the product.

...

(i) Actions committed to agency discretion

Actions under the authority of this section by the Secretary, by the Secretary of Defense, or by the Secretary of Homeland Security are committed to agency discretion.

...

(k) Relation to other provisions

If a product is the subject of an authorization under this section, the use of such product within the scope of the authorization shall not be considered to constitute a clinical investigation for purposes of section 355(i), 360b(j), or 360j(g) of this title or any other provision of this chapter or section 351 of the Public Health Service Act [42 U.S.C. 262].